**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| CHARLOTTE DEAN,<br><br>Plaintiff,<br><br>v.<br><br>NOVARTIS PHARMACEUTICALS CORPORATION<br><br>Defendants. | Civil Action No.:<br>2:20-cv-02755-JMV-MF<br><br>**JOINT PROPOSED DISCOVERY PLAN**<br><br>**Hon. Judge Mark Falk**<br><br>**(Conference Date: June 5, 2020)** |

**1. Set forth the name of each attorney appearing, the firm name, address and telephone number and facsimile number of each, designating the party represented.**

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*Attorneys for Defendant*
*Novartis Pharmaceuticals Corporation*

**2. Set forth a brief description of the case, including the causes of action and defenses asserted:**

**Plaintiff**:

This is an action brought by Charlotte Dean (hereinafter, "Plaintiff") against Defendant Novartis Pharmaceuticals Corporation (hereinafter, "NPC") to recover for injuries resulting from NPC's intentional failure to warn of dangerous and known risks associated with Tasigna® —a Novartis-manufactured prescription medication for treatment of chronic myeloid leukemia ("CML"). Specifically, NPC failed to warn of risks that Tasigna® caused several forms of severe, accelerated, and irreversible atherosclerotic-related conditions—i.e., the narrowing and hardening of arteries delivering blood to the arms, legs, heart, and brain. Despite warning doctors and patients in Canada of the risks of atherosclerotic-related conditions, NPC concealed, and continues to conceal, their knowledge of Tasigna®'s unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

After beginning treatment with Tasigna® and as a direct and proximate result of NPC's actions and inactions, Plaintiff suffered serious atherosclerotic-related injuries. Specifically, as a result of her use of Tasigna®, Plaintiff suffered from obstructive coronary artery disease. This condition required a percutaneous transluminal coronary angioplasty and stent placement. Plaintiff remains at significant risk of further complications as a result of her condition. As a result of her injuries, Plaintiff seeks damages including but not limited to the following:

a. General damages;
b. Medical and incidental expenses, including Plaintiff's need for life long care;
c. Losses related to Plaintiff's inability to pursue her usual occupation and activities;

d. Pain and suffering and emotional distress according to proof;
e. Punitive and exemplary damages;
f. Plaintiff's reasonable attorneys' fees and costs;
g. Prejudgment interest; and
h. Any other relief this Court deems appropriate.

**Defendant:**

NPC generally denies all allegations in the Complaint and Jury Demand ('the Complaint") of plaintiff. NPC's product Tasigna® is a cancer medication that is FDA-approved to treat patients with Philadelphia chromosome positive chronic myeloid leukemia ("CML"). CML is a blood cancer, one in which, over time, the body overproduces white blood cells. Unchecked, CML is a fatal disease. As of 2016, CML had a 69.2% five-year survival rate, up from 47.9% in 2000. The significant increase in survival between 2000 and 2016 paralleled the increase in the availability of tyrosine kinase inhibitor ("TKI") medicines, including NPC's Tasigna®. Tasigna® has been shown to be superior to its predecessor TKI treatment, Gleevec®, in treating CML. NPC denies that that there are any defects associated with Tasigna®.

Plaintiff will be unable to meet her burden to prove that Tasigna® can cause cardiovascular disease and that Tasigna® caused her alleged injuries. Plaintiff also will be unable to prove that the FDA-approved labeling for Tasigna® was inadequate. On January 22, 2014, Novartis updated the Tasigna® prescribing information in the United States to include a Warning & Precaution Section dedicated to Cardiac and Vascular Events. The Highlights of Prescribing Information on the first page stated:

> Cardiac and Vascular Events: Cardiovascular events including ischemic heart disease, peripheral arterial occlusive disease and ischemic cerebrovascular events have been reported in patients with newly diagnosed Ph+CML receiving nilotinib. Cardiovascular status should be evaluated and cardiovascular risk factors monitored and managed during Tasigna therapy.

NPC thus will request that judgment be entered in its favor and against plaintiff; that plaintiff's Complaint be dismissed, with prejudice; and that NPC be awarded costs of suit and reasonable attorney's fees as allowed by law and such further and additional relief as this Court may deem just and proper.

NPC's affirmative defenses and plaintiff's failures of proof include, but are not limited to, the following, and NPC reserves the right to amend them as the case progresses:

a. The labels and information accompanying Tasigna® were approved by the U.S. Food and Drug Administration, barring plaintiff's claims.
b. Federal law relating to the design, testing, producing, manufacturing, labeling, distributing, modeling, processing, and supply of Tasigna® preempts plaintiff's claims.
c. Punitive damages are not available in this case under New Jersey law. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343 (2001); *see also* N.J.S.A. § 2A:58C-5(c); *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004); *McDarby v. Merck & Co.*, 949 A.2d 223 (NJ Super. Ct. App. Div. 2008).

**3. Have settlement discussions taken place? Yes __X__ No _____.**

The parties, prior to filing of this lawsuit and others currently pending, engaged in multiple in-person discussions regarding whether plaintiff's claims could be resolved without litigation. Those discussions did not lead to a resolution.

**4. The parties [have __X__ have not _____] met pursuant to Fed. R. Civ. P. 26(f):**

**5. The parties [have _____ have not __X__] exchanged the information required by Fed. R. Civ. P. 26(a)(1). If not, state the reason therefor.**

The parties have agreed to exchange disclosures by June 5, 2020, which is 14 days after of the parties' Rule 26(f) conference, pursuant to Fed. R. Civ. P. 26(a)(1)(C)).

**6. Explain any problems in connection with completing the disclosures required by Fed R. Civ. P. 26(a)(1).** N/A

**7. The parties [have _____ have not __X__] conducted discovery other than the above disclosures. If so, describe.**

**8. Proposed Joint Discovery Plan:**

**(a) Discovery is needed on the following subjects:**

**Plaintiff**:

Prior to the commencement of this action, claims alleging atherosclerotic-related injuries caused by Tasigna® were filed against NPC in the Eastern District of California (Kristi Lauris v. Novartis AG et al., 1:16-cv-00393-LJO-SAB) and the Southern District of Florida (Dennis McWilliams v. Novartis AG et al., 2:17-cv-14302-RLR). Counsel for Plaintiff here did not appear in these actions. Both of these cases were resolved shortly before scheduled trial dates and after the completion of fact and expert discovery and subsequent denial of NPC's Summary Judgement Motion.

The parties are meeting and conferring as to the whether the discovery conducted in those cases may be applicable to the matter at bar. Plaintiff's counsel here does not have knowledge of the extent of this prior discovery and therefore reserves all rights to conduct discovery on all matters relevant to the claims and defenses herein. In order to facilitate this process, Plaintiff has requested an initial, informal exchange of certain information, which Defendant has agreed to consider. This information will further assist the parties in determining the scope of discovery that was completed in the prior actions and the additional discovery needed here. There is undoubtedly additional discovery that will be required to address the needs of this case.

For example, Plaintiff is aware that the timeframe covered by the discovery conducted in those two cases ended in approximately 2014. Plaintiff will seek additional discovery up to the present. There are likely to be additional areas of discovery relevant to the particular claims and defenses which are unique to this particular case which the parties intend to discuss.

At this time Plaintiff anticipates she will request discovery into Novartis' conduct surrounding the following areas as they relate to Tasigna® along with any additional areas of discovery that may be revealed as the case progresses:

a. Licensing;
b. Research & Development;
c. Patents;
d. Preclinical Development;
e. Clinical Development;
f. Medical Affairs;
g. Medical Coding;
h. Pharmacovigilance/Drug Safety;
i. Health Insurance Reimbursement;
j. Life Cycle Management;
k. Marketing;
l. Labeling;
m. Market Research;
n. Sales and Sales Training;
o. Key Opinion Leaders and/or Speakers' Bureaus;
p. Budgeting; and
q. Regulatory or compliance functions, including those related to the FDA and other foreign regulatory bodies

Finally, the Court should be aware there are approximately 30 cases involving similar claims currently pending in several Federal Districts across the United States, as well as in New Jersey State Court. The parties are discussing coordination of discovery in these actions.

**Defendant**:

NPC will, among other things, seek discovery on

- Plaintiff's medical condition, pre-existing medical conditions, family medical history, and risk factors for cardiovascular events;
- Plaintiff's alleged injuries and damages, including in the form of tax, employment, and social media records;
- Plaintiff's and prescribing physicians' knowledge of CML, Tasigna®, cardiovascular events, and all information obtained regarding the same.

Importantly, this case implicates an array of scientific, medical, and regulatory issues that will be the subject of wide-ranging expert reports and testimony. NPC anticipates that the parties will designate a dozen, or perhaps more expert witnesses (six per party, or more), which does not include the numerous treating physicians who will need to be deposed. NPC expects that it will seek evidentiary hearings on its *Daubert* motions that will challenge the admissibility of plaintiff's experts.

Moreover, discovery in this case includes the need to obtain copies of medical records from plaintiff's healthcare providers. The records collection process takes time, and is iterative in nature. As each set of records is received, they must be reviewed, and follow-up undertaken, to ensure that the provider has produced a complete set of records. Also, review of collected records inevitably leads to the identification of additional healthcare providers or locations of treatment, and new requests must be made to collect those. Although the parties work diligently to collect records, often facilities take significant amounts of time to respond to requests.

**(b) Discovery [should __x__ / should not _] be conducted in phases or be limited to particular issues. Explain.**

The parties request that expert discovery take place following the completion of fact discovery. NPC further requests that the depositions of plaintiffs' experts take place prior to the depositions of NPC's experts.

The parties are not asking the Court to limit discovery to particular issues at this time.

**(c) Proposed schedule:**

**(1) Fed. R. Civ. P. 26 Disclosures:** June 5, 2020.

**(2) E-Discovery conference pursuant to L. Civ. R. 26.1(d): on or before** July 10, 2020**.**

**(3) Service of initial written discovery: on or before** August 10, 2020**, which shall be responded to by** September 10, 2020**.**

**(4) Maximum of** 25 **Interrogatories, including subparts, with initial interrogatories to be served on or before** July 3, 2020**, which shall be responded to by** August 2, 2020**.**

**(5) Maximum of** 10 **depositions of fact witnesses to be taken by each party.**

The parties agree that the presumptive limit of 10 depositions applies only to fact witnesses, and that depositions of the parties' designated experts should not count toward the parties' limits. As detailed above, the parties are actively meeting and conferring regarding the discovery conducted in the two prior litigations. The number of depositions Plaintiff requests in this case will likely depend on that prior discovery. After the parties have met and conferred regarding previous discovery and depositions and what additional discovery is needed, Plaintiff will confer with NPC in an attempt to reach an agreement as to the number of additional depositions required at this time. The parties also anticipate that depositions of NPC's fact witnesses can be coordinated with those cases pending in other Federal Courts and the State of New Jersey, so as to avoid duplicative efforts. The parties reserve their right to seek additional fact depositions by agreement of the parties or by Court order.

**(6) Motions to amend or to add parties to be electronically filed by** July 22, 2020.

**(7) Factual discovery to be completed by** July 2, 2021 . **All fact witness depositions must be completed by the close of fact discovery. No discovery is to be issued or engaged in beyond that date, except upon application and for good cause shown.**

**(8) Plaintiff's expert reports due on** August 6, 2021 **. All expert reports must comport with the form and content requirements set forth in Rule 26(a)(2)(B). No expert shall testify at trial as to any opinions or base those opinions on facts not substantially disclosed in the expert's report.**

**(9) Plaintiff's expert depositions to be completed by** October 8, 2021**.**

**(10) Defendant's responsive expert reports due on** November 12, 2021**.**

**(11) Defendant's Expert depositions to be completed by** January 15, 2022**.**

(**11) Dispositive motions to be served within** 45 **days of completion of all discovery.**

**(d) Set forth any special discovery mechanism or procedure requested.**

NPC also requests that the Court plan to conduct an evidentiary hearing related to the expected *Daubert* issues in this case. NPC expects to include a formal request for a *Daubert* evidentiary hearing in its *Daubert* briefing.

**(e) A pretrial conference may take place on** July 18, 2022, or other date to be selected by the Court following resolution of any dispositive motions**.**

**(f) Trial date: August 8, 2022 (** X **Jury Trial;** **Non-Jury Trial).**

Plaintiff may propose this case be tried jointly with Gustin, et al. v. Novartis Pharmaceuticals Corporation, Civil Action No. 20-2753 (JMV). NPC would oppose any request, if one were made, to consolidate separate cases for trial.

**9. Do you anticipate any special discovery needs (i.e., videotape/telephone depositions, problems with out-of-state witnesses or documents, etc.)? Yes** **No** X (not at this time)**. If so, please explain.**

The parties anticipate the need to obtain out-of-state documentary discovery and to depose witnesses outside of New Jersey. NPC notes that current travel restrictions may complicate those efforts for some time (see question 12 below).

**10. Do you anticipate any issues about disclosure or discovery of electronically stored information, including the form or forms in which it should be produced? Yes** **No** X (not at this time)

**If so, how will electronic discovery or data be disclosed or produced? Describe any agreements reached by the parties regarding same, including costs of discovery, production, related software, licensing agreements, etc.**

**11. Do you anticipate entry of a Discovery Confidentiality Order? See L.Civ.R. 5.3(b) and Appendix S.**

NPC will seek the entry of a Confidentiality Order. Plaintiff does not anticipate entering into a global, sweeping confidentiality agreement. All of the documents on each party's exhibit lists in the *Lauris* case (which amounted to several thousand documents) were, by court order, filed in the public record, and NPC has no expectation of privacy in these and related documents. Plaintiff expects that the parties will address confidentiality on a case-by-case basis, and Plaintiff will notify Novartis of any non-public document it produces that Plaintiff intends to disclose to third parties not associated with the litigation of this matter. Plaintiff will negotiate with NPC in good faith on all confidentiality issues.

**12. Do you anticipate any discovery problem(s) not listed above? Describe. Yes _____ No _X_.**

**13. State whether this case is appropriate for voluntary arbitration (pursuant to Local Civil Rule 201.1 or otherwise) or mediation (pursuant to Local Civil Rule 301.1 or otherwise). If not, explain why and state whether any such procedure may be appropriate at a later time (i.e., after exchange of pretrial disclosures, after completion of depositions, after disposition or dispositive motions, etc.).**

The parties agree that this case is not appropriate for voluntary arbitration or mediation at this time. The parties agree to consider mediation following the resolution of dispositive motions.

**14. Is this case appropriate for bifurcation? Yes _____ No _X_.**

**15. An interim status/settlement conference (with clients in attendance), should be held in** (to be determined by Court)**.**

**16. We [do _____ do not _X_] consent to the trial being conducted by a Magistrate Judge.**

**17. Identify any other issues to address at the Rule 16 Scheduling Conference.**

None at this time.

/s/ Raymond C. Silverman 6/2/2020
Attorney(s) for Plaintiff Date

/s/ Melanie H. Muhlstock 6/2/2020
Attorney(s) for Plaintiff Date

| /s/ Andrew L. Reissaus | 6/2/2020 |
|---|---|
| Attorney(s) for Defendant | Date |

| /s/ Donald R. McMinn | 6/2/2020 |
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| Attorney(s) for Defendant | Date |

| /s/ Marina Plotkin | 6/2/2020 |
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